

**APPLICANT'S RESPONSE AND REMARKS**

Applicant sincerely thanks the Examiner for the attention to this application. Applicant appreciates and concurs with the Examiner's rejoinder of claims 38 and 39. With respect to the Claim Objection relating to the typographical error in claim 38 regarding the word "flavor", the currently presented claims have incorporated the appropriate correction. Further amendments are discussed below in context of the reason they have been made herein.

Regarding the rejection based on 35 USC § 112, Applicant respectfully disagrees that the claims as presented do not comply with the written description requirement. With respect to the Examiner's assertion that "non-saccharide excipient" is not supported, Applicant first asserts that one of skill in the art based on the specification would understand the term to mean an excipient that is not and does not contain a saccharide. This language was presented to make clear that only tablets with one saccharide are being claimed in this application. That said, the currently presented claims 32 and 36 have been amended to more clearly define the saccharides that are contemplated in the claimed invention and to very clearly specify that the defined excipients themselves can contain no saccharides. The specific list of saccharides as currently claimed is supported in the specification at least in paragraph 28. The specific list of excipients is consistent with the excipients utilized throughout the specification and examples. Further, to the extent the Examiner has suggested that corn starch, previously enumerated in the claims as one of the group of non-saccharide excipients, could be deemed by one of skill in the art as a saccharide, it has been removed from the list of non-saccharide containing excipients and included as a requirement within the "consisting of" language associated with the claimed tablets.

Regarding the Examiner's issue with respect to the examples in the specification being drawn to non-saccharide formulations (see p. 3 in the Office Action), there appears to be an error. As exemplified, each tablet contains a Fast Dissolve Granulation that, per Table 1 (specification p. 17) and disclosed in examples 6, 7, and 8, includes a saccharide. As such, tablets including saccharides are both disclosed and claimed in a consistent fashion and adequately supported.

In the second paragraph asserting the Examiner's bases for the 35 USC § 112 rejection, the issue with respect to corn starch is set forth and also an issue with claim 34 and the claiming of "one or more" low melting point compounds. Applicant, as set forth above and in the claim amendments, has addressed the issue with respect to corn starch. With respect to the issue of a lack of antecedent basis for "one or more" low melting point compounds, Applicant did not intend to be limited to a single low melting point compound. Indeed, the specification supports tablet compositions with more than one low melting point compound. See, e.g. the specification at paragraph 27. As such, independent claims 32 and 36 have been amended to more broadly claim "one or more" low melting point compounds and to provide the antecedent basis that Examiner pointed out was lacking.

The final issue raised by the Examiner with respect to 35 USC § 112 was with respect to the "consisting of" language presented in previously presented dependent claim 39. To correct this issue, claim 39 has been canceled and new claim 40 has been written to present the intended subject matter of claim 39 as an independent claim.

With respect to the Examiner's rejection under 35 USC § 103(a) based on Shimizu because "about 1.7 kP" is not so far from ... the hardness range disclosed by Shimizu," the claims as presented now limit the claimed tablets to ones with a hardness of less than 1.5 kP. This amendment is supported in the specification at, e.g., paragraph 9.

#### **Rejection Under 35 USC §103(a) – Mizumoto in view of Mauger**

Claims 32-39 stand rejected under 35 USC §103 over Mizumoto et al. (US 5,576,014, herein "Mizumoto") in view of Mauger et al. (US 5,728,403, herein "Mauger").

Applicants assert that the Examiner's bases for this rejection has been removed in light of the amended claims as presented. The current claim amendments unequivocally specify that the claimed compositions consist of a single saccharide and indeed specify the applicable saccharides. This is contrary to the teaching of Mizumoto. Indeed, a primary conclusion of Mizumoto is that "when a saccharide having low moldability or a saccharide having high moldability was used alone in the compression molding, the adequate hardness and the quick

disintegration and dissolution in the buccal cavity were not simultaneously obtained.” Col. 5, lines 18-22. As such, in context, Mizumoto teaches away from compositions as claimed herein.

Further, the citation to definitions at Column 6 is misplaced. The Examiner points to the definitions of the terms “saccharide having low moldability” and “saccharide having high moldability” as potentially including only a single saccharide. However, when these terms are used elsewhere in the specification, they are always used in combinations wherein more than one saccharide must be present. See Mizumoto column 12, line 24 through column 13, line 15.

As presented previously, the chart below shows the multiple saccharides present in the individual examples:

<u>Example</u>	<u>Saccharides</u>
1	maltose and mannitol
2	maltitol and mannitol
3	sorbitol and mannitol
4	maltose and lactose
5	oligosaccharide and mannitol
6	lactose, mannitol and maltitol
7	maltose and glucose
8	maltose and xylitol
9	maltose and sucrose
10	mannitol and lactose
11	lactose, mannitol and maltose
12	maltose and mannitol
13	maltose and mannitol
14	maltose and mannitol
15	maltose, mannitol and lactose
16	maltose and mannitol
17	maltose, mannitol and lactose
18	maltose and mannitol
19	maltose and mannitol (from Ex. 18) and more mannitol

As such, Mizumoto neither teaches or suggests that one saccharide is required (Mizumoto requires at least two saccharides with specified moldabilities).

Further Mizumoto neither teaches or suggests that a saccharide and a low melting point compound form a fast dissolve granulation; and/or that a saccharide in combination with a low melting point solid forms a fast dissolving granulation and/or that the fast dissolving granulation comprises about 30% to about 75% of the weight of the fast dissolve tablet as Applicants' claims require. As recognized by the Examiner, this and other elements of the claims currently presented are lacking from Mizumoto, but notwithstanding, the Examiner still asserts that missing elements in

terms of ranges and concentration would have been obvious and now requires the showing of an unexpected or surprising result. In response, first Applicant submits that the characteristics of the tablets as claimed would have been unexpected at the time of filing. However, this standard is not applicable since so many of the claimed limitations are missing from the cited art. Indeed, the key requirement that there only be a single saccharide is missing from the cited art. The requisite advantages of a low hardness tablet with the characteristics disclosed and claimed in this application are described throughout the application. See, e.g., paragraphs 7 and 8.

Further, contrary to the Examiner's argument per In re Aller that it would require "routine experimentation" to arrive that the claimed tablets, the Federal Circuit has repeatedly stated "there is no basis for concluding that an invention would have been obvious solely because it is a combination of elements that were known in the art at the time of the invention." See for example Smiths Industries Medical Sys., Inc. v. Vital Signs, Inc., 183 F.3d 1347, 1355, 51 U.S.P.Q.2d 1415, 1423 (Fed.Cir. 1999). The Federal Circuit also recognizes that "virtually all inventions are combinations of old elements... If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue." See, for example, In re Rouffet, 149 F.3d 1350, 1356, 47 U.S.P.Q.2d 1453, 1459 (Fed.Cir. 1998).

Merely because some of the elements of the claimed invention are disclosed in a prior reference is not enough to establish that the invention was obvious. The only way that one would arrive at the present invention is through the use of impermissible hindsight.

The Examiner's reliance on with respect to Mizumoto's failure to teach hydrogenated oils is also insufficient to correct other lackings in Mizumoto. Again, Mauger also does not disclose or suggest a combination including only a single saccharide. The Examiner continues to rely upon Mauger "to demonstrate the teaching that it is known to incorporate mixtures of mono-, di- and triglycerides, whereby the glycerides provide for taste-masking of drugs and enables a composition to melt at body temperature." (emphasis added). Mauger provides no teaching, suggestion, or motivation to use a single saccharide even in the coating disclosed in Mauger much less any other capacity. Further, Mauger provides no teaching disclosure or motivation to use a fast dissolve granulation in a tablet in any capacity coating or otherwise. Accordingly, Mauger does not disclose, suggest or provide motivation for combining saccharide with a low melting point solid form to a

fast dissolving granulation, and no teaching, suggestion or motivation for forming a tablet wherein about 30% to about 75% of the weight of the tablet is a fast dissolve granulation of a saccharide and a low melting point solid as Applicants' claims 32 and 38 require.

Thus Mauger neither teaches or suggests the elements needed to cure the identified deficiency of Mizumoto – namely Mauger does not teach or suggest that a single saccharide and a low melting point compound may be used to form a fast dissolving tablet composition and/or that a saccharide in combination with a low melting point solid forms a fast dissolving granulation and/or that the fast dissolving granulation comprises about 30% to about 75% of the weight of the tablet.

In view of at least these distinctions and the fact that Applicants have amended independent Claims 32 and 36 to clarify that only a single saccharide is required in the claims herein, Applicants respectfully request that the Examiner withdraw the rejection of independent claims 32 and 36 and claims 33-35, and 37 which variously depend from claim 33 and 36 under 35 USC §103(a) in view of Mizumoto (US 5,178,878) in view of Mauger et al. (US 5,728,403).

**Rejection Under 35 USC §103 (a) - Shimizu**

The Examiner has stated that claims 32 and 34-36 stand rejected under 35 USC §103 over Shimizu et al. (U.S. 6,299,904 B1, herein "Shimizu"). As above, amended independent claims 32 and 36 are presented for the Examiner's consideration. Applicants have attempted to remove any doubt that the claimed compositions encompass only compositions that contain a single saccharide. A further amendment to claims 32, 36, 38 and new claim 40 addresses the Examiner's concern that "about 1.7 kP" is not so far from ... the hardness range disclosed by Shimizu". The claims as presented now limit the claimed tablets to ones with a hardness of less than 1.5 kP. This amendment is supported in the specification at, e.g., paragraph 9.

Applicants believe that these amended claims further point out and distinguish Applicants' invention. Applicants respectfully request that the Examiner consider these proposed amendments and allow amended independent claims 32, 36, 38 and new claim 40 and the dependent claims which variously depend from these claims.

The Examiner has cited Col. 8, lines 5-8 of Shimizu for a tablet of hardness of about 2 to about 20 kg. Firstly, this hypothetical disclosure is not supported anywhere in the rest of Shimizu. None of the Shimizu examples have a hardness that comes close to the recited lower boundary of 2 kg. The lowest hardness actually exemplified in Shimizu is 4.2 kg in Working Example 5 (Col. 11, lines 35-36). The hardness range claimed by Applicants is consistent with the hardness measured for exemplary embodiments of Applicants' composition and is substantially lower than what is meaningfully disclosed by Shimizu. One skilled in the art recognizes that tablet hardness may impact a number of properties of a tablet including for example, processability, robustness and dissolution behavior. As the data presented in Example 8 shows, Applicants' composition can be formed into a tablet with substantially lower hardness than that of Shimizu.

Nonetheless, despite the failure by Shimizu to meaningfully enable one of skill in the art to create tablets with a hardness below 4.2 kg, the presently presented claims are directed to tablets with a hardness less than about 1.7 kP.

Furthermore, nowhere does Shimizu disclose or suggest the combination of a single saccharide and low melting point compound to form a fast dissolving granulation. Shimizu teaches a combination of one or more of a limited number of sugar alcohols with a very hydroscopic material hydroxypropylcellulose. Nowhere does Shimizu teach or suggest a fast dissolve granulation of a low melting point compound and a saccharide and/or that such a granulation should comprise about 30% to about 70% of the tablet by weight and/or that the amount of low melting point compound should be about 0.01% to about 2.5% (wt/wt) of the tablet. Accordingly, Shimizu does not set forth or infer every claim element of Applicants' claim 32. Nor does Shimizu provide any suggestion or motivation to prepare a fast dissolve granulation much less a fast dissolve granulation as described and claimed by applicants.

As claims 34 and 35 variously depend from claim 32, the present amendment to claim 32 reciting a hardness of less than 1.5 kP applies to claims 34-35. Accordingly, the amendment also further distinguishes claims 34-35 from Shimizu for the reasons discussed above.

With respect to claim 36, Shimizu does not teach the claimed limitation requiring that the low melting point compound be selected from hydrogenated vegetable oil, and partially hydrogenated vegetable oil. Indeed, Shimizu does not

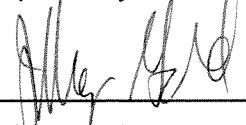
recognize the advantage of a low melting point compound at all, let alone the specifically claimed compounds herein.

In view of at least these distinctions, Applicants respectfully request that the Examiner withdraw the rejection of independent claims 32 and 36 and claims 34 and 35 which depend from claim 32 based on 35 USC §103 over Shimizu et al.

**CONCLUSION**

In view of the amended claim set presented herein and the above remarks, Applicants respectfully request that currently presented claims be entered and allowed. Should the Examiner believe that anything further is desired in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicant's representative at 973-660-5739.

Respectively submitted,

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